SENATE BILL No. 297

DIGEST OF INTRODUCED BILL

Citations Affected: IC 12-15; IC 12-23-18.

Synopsis: Opioid dependence treatment. Requires Medicaid coverage for inpatient detoxification for the treatment of opioid or alcohol dependence. Allows the mental health Medicaid quality advisory committee to make recommendations to the office of Medicaid policy and planning (office) concerning the development of a treatment protocol containing best practice guidelines for the treatment of opiate dependent patients. Limits Medicaid reimbursement for certain drugs prescribed for the treatment of pain. Specifies that the healthy Indiana plan includes coverage of counseling services for substance abuse treatment. Adds requirements for an opioid treatment program to meet in order to operate in Indiana. Requires the division of mental health and addiction (division) to adopt specified administrative rules concerning opioid treatment by an opioid treatment provider. Requires an opioid treatment program to provide specified information upon request by the division.

Effective: July 1, 2016.

Miller Patricia

January 7, 2016, read first time and referred to Committee on Health & Provider Services.

Introduced

Second Regular Session 119th General Assembly (2016)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2015 Regular Session of the General Assembly.

SENATE BILL No. 297

A BILL FOR AN ACT to amend the Indiana Code concerning human services.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 12-15-5-13, AS ADDED BY P.L.209-2015, SECTION 11, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 13. (a) The office shall provide coverage for treatment of opioid or alcohol dependence that includes the following:

(1) Counseling services that address the psychological and behavioral aspects of addiction.

(2) When medically indicated, drug treatment involving agents approved by the federal Food and Drug Administration for the:

(A) treatment of opioid or alcohol dependence; or

(B) prevention of relapse to opioids or alcohol after detoxification.

(3) Inpatient detoxification:

(A) in accordance with the most current edition of the American Society of Addiction Medicine Patient Placement Criteria; and

(B) when determined by the treatment plan to be medically necessary.

(b) The office shall:

(1) develop quality measures to ensure; and

(2) require a Medicaid managed care organization to report;

compliance with the coverage required under subsection (a).

(c) The office may implement quality capitation withholding of reimbursement to ensure that a Medicaid managed care organization has provided the coverage required under subsection (a).

(d) The office shall report the clinical use of the medications covered under this section to the mental health Medicaid quality advisory committee established by IC 12-15-35-51. The mental health Medicaid quality advisory committee may make recommendations to the office concerning this section, **including the development of a treatment protocol containing best practice guidelines for the treatment of opiate dependent patients. The treatment protocol must have the goal of opioid abstinence, when appropriate, and must include the following:**

(1) Appropriate clinical use of any drug approved by the federal Food and Drug Administration for the treatment of opioid addiction, including the following:

(A) Opioid maintenance.

(B) Opioid detoxification.

(C) Overdose reversal.

(D) Relapse prevention.

(E) Long acting, nonaddictive medication assisted treatment medications.

(2) A requirement for initial and periodic behavioral health assessments for each patient.

(3) Appropriate use of providing overdose reversal, relapse prevention, counseling, and ancillary services.

(4) Transitioning off agonist and partial agonist therapies, when appropriate, with the goal of opioid abstinence.

(5) Training and experience requirements for prescribers of drugs described in subdivision (1) in the treatment and management of opiate dependent patients.

(6) A requirement that prescribers obtain informed consent from a patient concerning all available opioid treatment options, including each option's potential benefits and risks, before prescribing a drug described in subdivision (1).

SECTION 2. IC 12-15-35-35 IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 35. (a) **Except as provided in IC 12-15-35.5-9,** before the board develops a program to place a single source drug on prior approval, restrict the drug in its use,

or establish a drug monitoring process or program to measure or restrict utilization of single source drugs other than in the SURS program, the board must meet the following conditions:

(1) Make a determination, after considering evidence and credible information provided to the board by the office and the public, that placing a single source drug on prior approval or restricting the drug's use will not:

(A) impede the quality of patient care in the Medicaid program; or

(B) increase costs in other parts of the Medicaid program, including hospital costs and physician costs.

(2) Meet to review a formulary or a restriction on a single source drug after the office provides at least fifteen (15) days notification to the public that the board will review the formulary or restriction on a single source drug at a particular board meeting. The notification shall contain the following information:

(A) A statement of the date, time, and place at which the board meeting will be convened.

(B) A general description of the subject matter of the board meeting.

(C) An explanation of how a copy of the formulary to be discussed at the meeting may be obtained.

The board shall meet to review the formulary or the restriction on a single source drug at least fifteen (15) days but not more than sixty (60) days after the notification.

(3) Ensure that:

(A) there is access to at least two (2) alternative drugs within each therapeutic classification, if available, on the formulary; and

(B) a process is in place through which a Medicaid recipient has access to medically necessary drugs.

(4) Reconsider the drug's removal from its restricted status or from prior approval not later than six (6) months after the single source drug is placed on prior approval or restricted in its use.

(5) Ensure that the program provides either telephone or FAX approval or denial Monday through Friday, twenty-four (24) hours a day. The office must provide the approval or denial within twenty-four (24) hours after receipt of a prior approval request. The program must provide for the dispensing of at least a seventy-two (72) hour supply of the drug in an emergency situation or on weekends.

(6) Ensure that any prior approval program or restriction on the

use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications.

(b) The board shall advise the office on the implementation of any program to restrict the use of brand name multisource drugs.

(c) The board shall consider:

(1) health economic data;

(2) cost data; and

(3) the use of formularies in the non-Medicaid markets;

in developing its recommendations to the office.

SECTION 3. IC 12-15-35.5-9 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 9. (a) Except as provided in subsection (c), the office may not reimburse under Medicaid for Subutex, Suboxone, or a similar trade name or generic of the drug prescribed for the treatment of pain or pain management, unless the prescriber is a physician licensed under IC 25-22.5 who:**

(1) has obtained a waiver from the federal Substance Abuse and Mental Health Services Administration (SAMHSA) and meets the qualifying standards required to treat opioid addicted patients in an office based setting; and

(2) has a valid federal Drug Enforcement Administration registration number and a Drug Enforcement Administration identification number that specifically authorizes treatment in an office based setting.

(b) The office may require prior authorization before a prescriber may prescribe a prescription drug described in subsection (a) for a Medicaid recipient.

(c) A physician licensed under IC 25-22.5 may prescribe a prescription drug described in subsection (a) for acute pain treatment and the office may reimburse for the drug if the treatment with the prescription drug is for less than ninety (90) days.

SECTION 4. IC 12-15-44.2-4, AS AMENDED BY P.L.209-2015, SECTION 13, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 4. (a) The plan must include the following in a manner and to the extent determined by the office:

(1) Mental health care services.

(2) Inpatient hospital services.

(3) Prescription drug coverage, including coverage of a long acting, nonaddictive medication assistance treatment drug if the drug is being prescribed for the treatment of substance abuse.

(4) Emergency room services.

(5) Physician office services.
(6) Diagnostic services.
(7) Outpatient services, including therapy services.
(8) Comprehensive disease management.
(9) Home health services, including case management.
(10) Urgent care center services.
(11) Preventative care services.
(12) Family planning services:
(A) including contraceptives and sexually transmitted disease testing, as described in federal Medicaid law (42 U.S.C. 1396 et seq.); and
(B) not including abortion or abortifacients.
(13) Hospice services.
(14) Substance abuse services, **including counseling services described in IC 25-23.6-1-5.9.**
(15) A service determined by the secretary to be required by federal law as a benchmark service under the federal Patient Protection and Affordable Care Act.

(b) The plan may do the following:
(1) Offer coverage for dental and vision services to an individual who participates in the plan.
(2) Pay at least fifty percent (50%) of the premium cost of dental and vision services coverage described in subdivision (1).

(c) An individual who receives the dental or vision coverage offered under subsection (b) shall pay an amount determined by the office for the coverage. The office shall limit the payment to not more than five percent (5%) of the individual's annual household income. The payment required under this subsection is in addition to the payment required under section 11(b)(2) of this chapter for coverage under the plan.

(d) Vision services offered by the plan must include services provided by an optometrist.

(e) The plan must comply with any coverage requirements that apply to an accident and sickness insurance policy issued in Indiana.

(f) The plan may not permit treatment limitations or financial requirements on the coverage of mental health care services or substance abuse services if similar limitations or requirements are not imposed on the coverage of services for other medical or surgical conditions.

SECTION 5. IC 12-23-18-0.5, AS AMENDED BY P.L.1-2009, SECTION 108, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 0.5. (a) An opioid treatment

program shall not operate in Indiana unless **the opioid treatment program meets the following conditions:**

(1) ~~the opioid treatment program~~ Is specifically approved and the opioid treatment facility is certified by the division. ~~and~~

(2) ~~the opioid treatment program~~ Is in compliance with state and federal law.

(3) Provides treatment for opioid addiction using a drug approved by the federal Food and Drug Administration for the treatment of opioid addiction, including:

(A) opioid maintenance;

(B) detoxification;

(C) overdose reversal;

(D) relapse prevention; and

(E) long acting, nonaddictive medication assisted treatment medications.

(4) Is:

(A) enrolled as a Medicaid provider under IC 12-15;

(B) enrolled as a healthy Indiana plan provider under IC 12-15-44.2; and

(C) a provider credentialed to accept insurance from a health plan (as defined in IC 4-1-12-2), including:

(i) a policy of accident and sickness insurance (IC 27-8-5); and

(ii) a health maintenance organization (IC 27-13).

(b) Separate specific approval and certification under this chapter is required for each location at which an opioid treatment program is operated. **If an opioid treatment program moves the opioid treatment program's facility to another location, the opioid treatment program's certification does not apply to the new location and certification for the new location under this chapter is required.**

SECTION 6. IC 12-23-18-5, AS AMENDED BY P.L.7-2015, SECTION 38, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 5. (a) The division shall adopt rules under IC 4-22-2 to establish the following:

(1) Standards for operation of an opioid treatment program in Indiana, including the following requirements:

(A) An opioid treatment program shall obtain prior authorization from the division for any patient receiving more than seven (7) days of opioid **maintenance** treatment medications at one (1) time and the division may approve the authorization only under the following circumstances:

(i) A physician licensed under IC 25-22.5 has issued an order for the opioid treatment medication.

(ii) The patient has not tested positive under a drug test for a drug for which the patient does not have a prescription for a period of time set forth by the division.

(iii) The opioid treatment program has determined that the benefit to the patient in receiving the take home opioid treatment medication outweighs the potential risk of diversion of the take home opioid treatment medication.

(B) Minimum requirements for a licensed physician's regular:

(i) physical presence in the opioid treatment facility; and

(ii) physical evaluation and progress evaluation of each opioid treatment program patient.

(C) Minimum staffing requirements by licensed and unlicensed personnel.

(D) Clinical standards for the appropriate tapering of a patient on and off of an opioid treatment medication.

(2) A requirement that, not later than February 28 of each year, a current diversion control plan that meets the requirements of 21 CFR Part 290 and 42 CFR Part 8 be submitted for each opioid treatment facility.

(3) Fees to be paid by an opioid treatment program for deposit in the fund for annual certification under this chapter as described in section 3 of this chapter.

The fees established under this subsection must be sufficient to pay the cost of implementing this chapter.

(b) The division shall conduct an annual onsite visit of each opioid treatment program facility to assess compliance with this chapter.

(c) Not later than April 1 of each year, the division shall report to the general assembly in electronic format under ~~IC 5-14-3~~ **IC 5-14-6** the number of prior authorizations that were approved under subsection (a)(1)(A) in the previous year and the time frame for each approval.

SECTION 7. IC 12-23-18-5.3 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: **Sec. 5.3. Subject to federal law and consistent with standard medical practices in opioid treatment for substance abuse, the division shall adopt rules under IC 4-22-2 concerning opioid treatment by an opioid treatment provider, including the following:**

(1) A requirement that the opioid treatment provider periodically review with the patient the patient's treatment plan. In the review, the opioid treatment provider shall

consider changes to the plan with the goal, when appropriate, of opioid abstinence.

(2) Treatment protocols containing best practice guidelines for the treatment of opiate dependent patients, including the following:

(A) Appropriate clinical use of all drugs approved by the federal Food and Drug Administration for the treatment of opioid addiction, including the following when available:

(i) Opioid maintenance.

(ii) Detoxification.

(iii) Overdose reversal.

(iv) Relapse prevention.

(v) Long acting, nonaddictive medication assisted treatment medications.

(B) Requirement of initial and periodic behavioral health assessments for each patient.

(C) Appropriate use of providing overdose reversal, relapse prevention, counseling, and ancillary services.

(D) Transitioning off agonist and partial agonist therapies with the goal, when appropriate, of opioid abstinence.

(E) Training and experience requirements for providers who treat and manage opiate dependent patients.

(F) Requirement that a provider who prescribes opioid medication for a patient periodically review INSPECT (as defined in IC 35-48-7-5.2) concerning controlled substance information for the patient.

SECTION 8. IC 12-23-18-8, AS ADDED BY P.L.131-2014, SECTION 5, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2016]: Sec. 8. (a) As used in this section, "dispense" means to deliver a controlled substance to an ultimate user.

(b) Subject to the federal patient confidentiality requirements under 42 CFR Part 2, when an opioid treatment program dispenses a controlled substance designated by the Indiana board of pharmacy under IC 35-48-2-5 through 35-48-2-10, the opioid treatment program shall provide the following information upon request from the division:

(1) The medications dispensed by the program.

(2) The medication delivery process, which includes whether the medication was in liquid, film, or another form.

(3) The number of doses dispensed of each medication.

(4) The dosage quantities for each medication.

(5) The number of patients receiving take home medications.

(6) The number of days of supply dispensed.

(7) Patient demographic information for each medication, including gender, age, and time in treatment.

(8) The dispenser's United States Drug Enforcement Agency registration number.

(9) The average number of patients served by:

(A) the opioid treatment program; and

(B) each employed or contracted prescriber of the opioid treatment program.

(10) The number of patients and the average length of treatment for each medication dispensed by the opioid treatment program.

(11) The number of patients successfully transitioned to opioid abstinence, including the use of long acting, nonaddictive medication for relapse prevention.

(12) A summary of INSPECT (as defined in IC 35-48-7-5.2) data reported regarding opioid and benzodiazepine use for patients receiving treatment on each of the medications dispensed by the opioid treatment program.

(c) An opioid treatment program shall provide the information required under this section to the division in a manner prescribed by the division.

(d) The division shall annually report the information collected under this section to the legislative council in an electronic format under IC 5-14-6 not later than October 1.